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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,407	08/23/2006	Takayuki Souta	086039-0016	7014
20277 7590 10/20/2010 MCDERMOTT WILL & EMERY LLP 600 13TH STREET, N.W. WASHINGTON, DC 20005-3096				
EXAMINER				
FARDANESHI, MARJAN				
ART UNIT		PAPER NUMBER		
4123				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/590,407

Applicant(s)

SOUTA ET AL.

Examiner

MARJAN FARDANESH

Art Unit

4123

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08/23/2006.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-13 is/are rejected.
7) ☒ Claim(s) 11 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 08/23/2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/GC/08)
Paper No(s)/Mail Date See Continuation Sheet
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

Continuation of Attachment(s) 3. Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :08/02/2010,08/23/2006,08/07/2009.

DETAILED ACTION

Specification

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract contains 158 words and also contains "means of applying white a light" and "means of plotting".

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).

- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Except for the "brief description of the drawings" the headings of the application differ from the headings above. Also, the "brief description of the drawings" should appear between brief summary of the invention and detailed description of the invention.

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The preamble of each of the claims recites, "measuring a superficial chemical species." Claim 12, "means for detecting a spectrum of white light reflected from two or more positions on said superficial chemical species." (Even if the spectroscope is a means for detecting a spectrum of white light it would be limited to one position at any given time not two as claimed.)
3. The amendment filed August 23, 2006 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: In paragraph [0005] recitation of projecting the data ...except for the first principal component. Note also, the sentences "In the foregoing ... and reduced hemoglobin." added to paragraph 0006.

Applicant is required to cancel the new matter in the reply to this Office Action.

Drawings

4. Color photographs and color drawings are not accepted unless a petition filed under 37 CFR 1.84(a)(2) is granted. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and, unless already present, an amendment to include the following language as the first paragraph of the brief description of the drawings section of the specification:

The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings and black and white photographs have been satisfied. See 37 CFR 1.84(b) (2).

Claim Objections

Claim 11 objected to because of the following informalities: spelling error in the last line of claim 11 where it says "to ".for the purpose of examination the examiner assumed the applicant meant "to". Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact

terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant application is the national stage of an international application filed February 22, 2005. Any claimed subject matter must find support in the international application as filed on February 22, 2005. The following claimed limitations comprise new matter because they are not supported in the international application as filed on February 22, 2005:

Claim 1, lines 10 and 11, "projecting the data of each position onto a direction of the eigenvector of at least one of said principal components" (as disclosed the projection is onto each of at least three principal components); lines 10-12, "except said first principal component" (as disclosed the projection is onto each of the principal components); lines 10-13 "to measure at least one of the concentration of the superficial species" (as disclosed the concentration of melanin and talaporfin are being measured but these are not disclosed as being superficial species.); and lines 11-13, "measure ...a concentration difference there between".

Claim 2, "measured from one spectrum of light". (Applicant doesn't provide support in specification for one spectrum of light).

Claims 4-6 applicant claims range within range. Appropriate correction is required.

Claim 11, "while a data of at least one position on said biological surface is projected onto the directions of the eigenvectors of said second and third principal components to display a change of magnitude thereof with time". (As disclosed the projection is onto each of at least three principal components).

Claim 12, "projecting the data of each position onto a direction of the eigenvector of at least one of the principal components" (as disclosed the projection is onto each of at least three principal components).

"except said first principal component" (as disclosed the projection is onto each of the principal components)

"measure at least one of the concentration of the superficial chemical species on said biological surface and a concentration difference there between" (as disclosed the concentration of melanin and talaporfin are being measured, not a concentration of a superficial chemical species)

For the purpose of examination, the newly added subject matter will not be afforded the filing date of the international application but will be afforded the date of the amendment.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The preamble of each of the claims recites, "measuring a superficial chemical species." The metes and bounds" of this phrase is not clear because the specification is directed to measuring a biological surface. The specification is silent as to what encompasses "a superficial chemical species".

8. Claim 12, line 15, "said biological surface lacks antecedent basis." Further regarding Claim 12, claim elements "means for irradiating, means for detecting a spectrum of white light reflected from two or more positions on said superficial chemical species, means for plotting, means for obtaining and means for displaying" are means (or step) plus function limitations that invoke 35 U.S.C. 112, sixth paragraph. However, the written description fails to clearly link or associate the disclosed structure, material,

or acts to the claimed function such that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function. Applicant is required to:

- (a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or
- (b) Amend the written description of the specification such that it clearly links or associates the corresponding structure, material, or acts to the claimed function without introducing any new matter (35 U.S.C. 132(a)); or
- (c) State on the record where the corresponding structure, material, or acts are set forth in the written description of the specification that perform the claimed function. For more information, see 37 CFR 1.75(d) and MPEP 2181 and 608.01(o).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1-6, 10 and 11 are rejected under 35 U.S.C. 103(a) as being obvious over WO 03/043492 (cited by applicants) in view of U.S. Patent No. 6,587,702 to Ruchti et al.

With respect to claim 1, WO '492 discloses a method of measuring selected tissue (i.e. superficial chemical species) which comprises the steps of: irradiating a white light to a biological surface as a sample (p.3 lines 19-20); detecting a spectrum of the white light reflected from two or more positions on said biological surface (p.3, lines 21-28); plotting an absorbance of said spectrum to a spectral multi-dimensional space of light (p. 12 lines 21-25); and conducting a multivariate analysis of a data on said spectral multi-dimensional space obtained from said two or more positions to obtain eigenvectors of at least first, second and third principal components(p.11 line 16- p.12 line 15).

WO '492 discloses each and every limitation of the claim, but does not disclose the step of "...projecting the data of each position onto a direction of the eigenvector of at least one of said principal components except said first principal component..." Ruchti et al. teaches projecting data of each position onto eigenvectors in order to detect spectral outlier through principal component analysis (column 7 line 65- column 8, line 25). Since limited number of eigenvectors are taught by Ruchti et al, it would have been obvious to one of ordinary skill in the art at the time of the invention to simplify calculations by eliminating any one or more of the principal components such as a first principal component with predictable results.

With respect to claim 2, WO '492 discloses at least one of the amounts of a plurality of the selected tissues (i.e. superficial chemical species) and a concentration difference therebetween is measured from one spectrum of light (page 3 lines 21, 22).

With respect to claim 3, WO '492 discloses hemoglobin (page 22, lines 26-31). In the in vivo environment, It is inherent that all hemoglobin includes oxygenated hemoglobin and or reduced hemoglobin.

With respect to claim 4, WO '492 discloses the multivariate analysis is conducted with said spectrum of light having wavelength bands of 500 to 600nm and 500 to 850nm (p.6 lines 29-31).

With respect to claim 5, WO '492 discloses the multivariate analysis is conducted with said spectrum of light having wavelength bands of 500 to 600nm and 700 to 780nm (p.6 lines 29-31).

With respect to claim 6, WO '492 discloses the multivariate analysis is conducted with said spectrum of light having wavelength bands of 500 to 600nm, 500 to 850nm and 700 to 780nm(p.6 lines 29-31).

With respect to claim 10, WO '492 discloses the multivariate analysis is conducted with said spectrum of light having a basic wavelength band of 700nm or above (p.6 lines 29-31).

With respect to claim 11, WO '492 discloses the multivariate analysis is conducted (p.11 line 16- p.12 line 15) with said spectrum of light having basic wavelength bands of 500 to 600nm and 500 to 850nm (p.6 lines 29-31 and displaying a change of magnitude thereof with time (figures 6, 4 8, 10, 11). Regarding the limitation of a data of at least

one position on said biological surface is projected onto the directions of the eigenvectors of said second and third principal components, this limitation is met by the modification of WO '492 in view of Ruchti et al. as discussed in the rejection of Claim 1 above(page 9, 2nd paragraph).

11. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being obvious over WO 03/043492 in view of U.S. Patent No. 6,587,702 to Ruchti et al.

With respect to claim 12, WO '492 discloses an apparatus for measuring a superficial chemical species comprising:

a means for irradiating a white light (wavelength range of WO '492 overlaps applicants range) to the superficial chemical species as a sample (p.4 lines 6-8);

a means for detecting a spectrum of the white light reflected from two or more positions on said superficial chemical species (p.4 lines 9, 10, 11-24);

a means for plotting an absorbance of said spectrum to a spectral multi-dimensional space of light (p.12 lines 21-25);

a means for obtaining eigenvectors of at least first, second and third principal components by conducting a multivariate analysis of data on said spectral multi-dimensional space obtained from said two or more positions (p.11 line 16-p.12 line 20);

a means for displaying a magnitude of the component of said data on a gray scale or in colors according to the magnitude, on a two-dimensional screen (page 4, lines 11-24 and figures 6, 4 8, 10, 11).

WO '492 taught each and every limitation of the claim, but does not disclose the limitation of "...projecting the data of each position onto a direction of the eigenvector of

at least one of said principal components except said first principal component..."

Ruchti et al. teaches projecting data of each position onto eigenvectors in order to detect spectral outlier through principal component analysis (column 7 line 65- column 8, line 25). Since limited number of eigenvectors are taught by Ruchti et al, it would have been obvious to one of ordinary skill in the art at the time of the invention to simplify calculations by eliminating one of the principal components such as the first principal component with predictable results.

With respect to claim 13, WO '492 discloses the means for irradiating a white light is provided integrally with a means for condensing reflection from two or more positions on said superficial chemical species sample by combining them with an optical fiber (p.6 lines 14-17).

12. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO '492 in view of Ruchti et al. as applied to claims 1-6, 10 and 11 above, and further in view of PGPUB 2003/0032064 to Soller et al. WO '492 as modified by Ruchti et al. fails to disclose the step of "wherein said multivariate analysis is conducted with a wavelength band including an absorption wavelength band specific to melanin; and a melanin concentration is predicted from a score of an eigenvector corresponding to melanin and a calibration curve of a score obtained from a sample whose melanin concentration is known." Soller et al. teaches similar spectral analysis using a wavelength bandwidth

within the range 400nm-800nm in order to present corrected spectra. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of WO '492 in view of Ruchti et al. to include the spectral analysis of melanin in order to present corrected spectra as taught by Soller et al (paragraph 17).

13. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO '492 in view of Ruchti et al. as applied to claims 1-6, 10 and 11 above, and further in view of PGPUB 2004/0243198 to Heacock et al. Regarding Claim 8, WO '492 and Ruchti et al. do not disclose use of a light-sensitive substance having the claimed wavelength bands. Heacock teaches the use of a light-sensitive substance (the photoreactive compounds or photosensitizers of Heacock) so that an eye may be examined (paragraph 0007) including talaporfin (paragraph 0044). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of WO '492 in view of Ruchti et al. to include the use of a light-sensitive substance in order to examine an eye as taught by Heacock. Regarding the claimed wavelength bands, Soller teaches the claimed wavelength bands (paragraph 0044).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARJAN FARDANESH whose telephone number is (571)270-5508. The examiner can normally be reached on Monday Thursday 8:00-17:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Derris Banks can be reached on (571)272-4419. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Marjan Fardanesh/

/Derris H Banks/
Supervisory Patent Examiner, Art Unit 3729